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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,165	11/19/2001	Michael Zeppezauer	44011.010700	8263

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/988,165	ZEPPEZAUER ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *3-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, remarks, and substitute specification filed 7/06/07 are acknowledged.

2. Claims 3-14 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions.

Claims 1 and 2 are being acted upon.

3. The specification stands objected to for the introduction of new matter into the specification. As set forth previously, In the instant amendment at pages 12 and 13 (paragraph 64) Applicant has added pharmaceutical compositions comprising numerous peptide species that do not appear in the specification as filed.

Applicant asserts that the "SEQ ID NO:1" of the specification as filed actually encompassed peptides 1_1 - 1_7, now SEQ ID NOS:1 and 4-9.

Applicant has provided no support for the assertion. Accordingly, the objection stands. Also note that an additional amendment to paragraph 64 has been submitted comprising additional new matter ("SEQ ID NO:1" has been amended to read "SEQ ID NO:1 to 9").

4. The declaration stands objected to because numerous uninitialed changes have been made. A new declaration is required.

Applicant indicates that a new declaration is forthcoming.

5. In view of Applicant's amendment the previous rejections under the second paragraph of 35 U.S.C. 112 has been withdrawn.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 2 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth previously, A review of the instant specification shows that the peptides of the claims are fragments of histon [sic] proteins. In particular, the elected peptide of SEQ ID NO:6 appears to be a fragment consisting of amino acids 195-220 of the human histone H1 protein. The peptides are asserted to comprise antigenic determinants involved in rheumatic autoimmun [sic] diseases including systemic lupus erythematosus (SLE) rheumatoid arthritis (RA), systemic sclerosis, and sclerodermia [sic]. The peptides are disclosed as being used for the diagnosis and treatment of said diseases.

Regarding the treatment of rheumatic autoimmune diseases, the specification offers just a single paragraph at page 12 wherein it is disclosed that diseases such as SLE, RA, and scleroderma can be treated by the administration of the claimed peptides. No data is disclosed, and indeed, no theory or mechanism by which the peptides might provide an effective treatment is even proposed. Accordingly, it would take undue trials and errors to employ the claimed invention for the treatment of any disease.

Regarding the diagnosis of disease, the specification discloses only that a combination of H1 (187-211) (presumably this represents amino acids 187-211 of the human H1 histone protein) and H2B (1-35) (presumably this represents amino acids 1-35 of the human H2B histone protein) peptides bound antibodies from the sera of certain patients. Note it is not even clear how many patients of what type were tested because at page 7 the specification discloses that 122 SLE patients were tested whereas at page 8 the specification discloses that just 80 SLE patients and 42 "rheumatic" patients were tested. Regardless, the peptides of the assay were not the peptide of the claimed invention. Accordingly, the results disclosed in the specification disclose nothing regarding the use of the claimed peptide for the diagnosis of disease.

Thus, in view of the quantity of experimentation necessary, the lack of sufficient guidance in the specification, the lack of sufficient working examples, i.e., the specification discloses no data relevant to the use of the claimed peptide, the unpredictability of the art, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Applicant's arguments, filed 7/06/07, have been fully considered but they are not persuasive. Applicant argues that the peptides of the claims an be used in ELISAs and to form monoclonal antibodies (mAbs) directed against autoantibodies of SLE patients.

Regarding the use of the peptides of the instant claims in the diagnosis of disease, in particular the diagnosis of SLE employing the peptide of the elected species (SEQ ID NO:6), see the rejection above. Said use is not enabled. Regarding the production of monoclonal antibodies as set forth in applicant's

arguments, said mAbs would necessarily comprise anti-idiotypic (α-id) antibodies. The production of α-id mAbs is not routine, nor is their use. The instant specification has not disclosed that said antibodies could be produced in the instant context, nor if produced, that said antibodies would function in any particular treatment or diagnosis. A set forth in *Rasmusson v. SmithKline Beecham Corp.*, 75 USPQ2d 1297, 1302 (CAFC 2005), enablement cannot be established unless one skilled in the art "would accept without question" an Applicant's statements regarding an invention, particularly in the absence of evidence regarding the effect of a claimed invention. Specifically:

> "As we have explained, we have required a greater measure of proof, and for good reason. If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis."

Thus, in view of the quantity of experimentation necessary, the lack of sufficient guidance in the specification, the lack of sufficient working examples, i.e., none, it would take undue trials and errors to practice the claimed invention.

8. The following is a new ground of rejection necessitated by Applicant's amendment.

9. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter written description rejection.

Specifically, no support for the peptide of the claim, comprising limitations such as "from 8 to 24 amino acids" or "five contiguous amino acids" has been cited and none has been found.

10. No claim is allowed.

11. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

13. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

7/28/09

G.R. Ewoldt, Ph.D.
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